UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,011	03/25/2004	Palpu Pushpangadan	09755-0019 US1	7730

23973 7590 04/19/2006

DRINKER BIDDLE & REATH
ATTN: INTELLECTUAL PROPERTY GROUP
ONE LOGAN SQUARE
18TH AND CHERRY STREETS
PHILADELPHIA, PA 19103-6996

EXAMINER	
ROBERTS, LEZAH	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/810,011	PUSHPANGADAN ET AL.	
	Examiner	Art Unit	
	Lezah W. Roberts	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) *17-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 32-46* is/are rejected.

7)☒ Claim(s) *16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Requirement for Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16 and 32-46, drawn to a synergistic herbal oro-dental care composition and method of using the composition, classified in class 424, subclasses 736, 750, 761 and 770.

II. Claims 17-31, drawn to process of preparing a synergistic herbal oro-dental care composition, classified in class 426, subclass 425.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the composition may be processed by using oil extracts as opposed to the powders.

Because these inventions are independent or distinct for the reasons given above, the inventions require a different field of search (see MPEP § 808.02) and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Notice of Potential Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election of Species

This application contains claims directed to the following patentably distinct species: powder, paste, gel, dental pack, dental floss, mouthwash, and chewing gum. The species are independent or distinct because each dental form requires different components to carry out different effects, for example a mouthwash would not contain a gum base like a chewing gum and would not be chewed.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 32 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

During a telephone conversation with Daniel Monaco on April 4, 2006 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-16 and 32-46. Affirmation of this election must be made by applicant in replying to this Office action. Claims 17-31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

The disclosure is objected to because of the following informalities: the specification has some grammatical errors. For example in the first line on page 1, an "a" should be placed in front of "synergistic" or an "s" should be added to the end of "composition". It is advised for the Applicant to proof read the specification and make any necessary corrections.

Appropriate correction is required.

Claims

Claim Objections

Claim 16 is objected to because of the following informalities: several spelling errors have been made, for example "mucus" should read "mucous". Several other spelling errors exist. Appropriate correction is required.

Claim Rejections - 35 USC § 112/35 USC § 101 – Use Claims

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 32-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 32-46 provides for the use of an oro-dental care composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 32-46 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103 - Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Preliminary Note:

The term synergistic has not been defined with in the disclosure therefore it is assumed the term is used according to its dictionary meaning. According to Answers.com, synergistic means "The combined action of two or more processes is greater than the sum of each acting separately".

1) Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farooqi et al. (US 6,264,926) in view of Lawlor (US 2003/0103914) and Thiebaud (FR 2 509 609).

Farooqi et al. teach dental composition, mainly tooth powders for treatment of pyorrhea, yellowing/staining of teeth and sensitivity. The compositions comprise *Zanthoxylum armatum*, which is useful for toothaches. It comprises from 20 to 25% of the composition. The powder of *Zanthoxylum armatum* is obtained from its flowers, leaves, roots or fruits, which encompasses claim 5. The composition also comprises an antiseptic, a compound to improve odor, a fragrance and an astringent. The reference also list common ingredients used in toothpowders found in India. They include *Azadirachta indica* have antiseptic and analgesic action (col. 3, lines 19-24). It can be assumed the *Azadirachta indica* is a powder because it is incorporated into a tooth

powder and it originates from twig. Also used in toothpowders is rice husk, which is also *Oriza sativa* (col. 4, table). The antiseptic used in the disclosed compositions was *Zingiber officinale* at a concentration of 25 to 30% of the composition. The reference differs from the instant claims insofar as it does not disclose using *Zanthoxylum armatum* in combination with *Citrus karma*, *Azadirachta indica* and *Oryza sativa*.

Lawlor teaches oral compositions that comprise an effective amount of an antibacterial seed or pulp extract from the Citrus plant family (paragraph 0002). These compositions are used to treat halitosis, which encompasses claim 16. The products are prepared in stable confectionery forms and portable oral care, which provides comparable benefits to frequent brushing. These forms include toothpaste, dentifrice, mouthwash or mouth rinses, topical oral gels, denture cleanser, mouth spray, dental floss, confectionery including chewing gum and lozenge, and the like, which encompasses claim 2. When the plant extracts are in conjunction with other anti-plaque agents the combination results in a greater plaque reduction than would be seen with either active alone. The citrus extracts also have malodor benefits (paragraph 0012). When combined with a metal, they improve the malodor benefits of the composition (paragraph 0014). Decrease in hypersensitivity occurs when citrus extracts are used in combination with hypersensitivity agents (paragraph 0013). The citrus extract may comprise from 0.0001 to about 30% of the oral composition, which encompasses the instant claims, and are obtained from the seed or pulp. The compositions also comprise an oral care active selected from the group consisting of anti-calculus agents; anti-plaque agents; fluoride ion source; desensitising agents; oral malodour control agents;

and mixtures thereof; and a pharmaceutically acceptable carrier, which encompasses claim 8. The compositions may comprise ethanol as a warming agent as recited in claim 9 and peppermint oil as a flavoring agent as recited in claims 10-11. Silica abrasives may also be used in the compositions with a particle size ranging from 0.1 to 30 microns (paragraph 0093), which encompasses claim 12. Antibacterial extracts, which contain organic acids (0045), and anticalculus components include acetic acids such as ethylenediaminetetraacetic acid are also used in the compositions (paragraph 0058). Although the reference does not use *Citrus karna* specifically, it list examples of various citrus plants that may be used and also discloses any citrus plant may be used in the compositions. According to Atlas of Florida Vascular Plants (http://www.plantatlas.usf.edu/synonyms.asp?plantID=1987, *Citrus karna* is grown in India; therefor it would be obvious to have used this citrus species in oral care products made in India. The reference differs from the instant claims insofar as it does not disclose using citrus extract in combination with *Zanthoxylum armatum, Azadirachta indica* and *Oryza sativa*.

Thiebaud teaches oral compositions comprising carbon black. It was taught carbon black enhanced the whitening of teeth. Although the carbon black was not obtained from *Oriza sativa*, carbon black is the same no matter the source. The reference states the carbon black may be obtained from vegetables. It also comprised from 20 to 60% or the composition. The reference differs from the instant claims insofar as it does not disclose using the carbon black in combination with *Zanthoxylum armatum, Azadirachta indica* and *Citrus karna*.

It would have been obvious to one of ordinary skill in the art to have added *Citrus karma, Azadirachta indica* and carbon black from *Oryza sativa* in the toothpowders of the primary reference motivated by the desire to produce a toothpaste or toothpowder with the additive effects of treating toothaches with *Zanthoxylum armatum*, treating bad breath and adding flavoring with *Citrus karna*, whitening teeth with carbon black from *Oriza sativa*, and killing germs and treating pain with *Azadirachta indica*, as taught by the combined references.

2) Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farooqi et al. (US 6,264,926) in view of Lawlor (US 2003/0103914) and Thiebaud (FR 2 509 609) as applied to claims 1-13 and 16 above, and further in view of Melman (US 2002/0156130).

The combined references are discussed above. The combined references differ from the instant claims insofar as they do not teach using acetic acid as an organic acid and cinnamon-clove beads as flavoring.

Melman teaches multi-functional dental compositions that treat dental plaque and carie formation and inhibit tooth decay and brighten/whiten teeth. The compositions of this invention comprise organic acids such as acetic acid and salts thereof, which can be combined with pharmaceutically acceptable carriers or diluents to be administered in the form of conventional dental compositions. The acetic acid is required to obtain effective inhibition of plaque and other bacteria (paragraph 0020). This encompasses claim 13.Other acids may be used in place of acetic acid such as

ethylenediaminetetraacetic acid (paragraph 0017). Suitable flavorings include both natural and artificial flavors, and mints such as peppermint, citrus flavors such as orange and lemon, artificial vanilla, cinnamon, various fruit flavors and the like. In one embodiment the flavoring agent comprises cinnamon-clove beads. Such beads can be additionally filled with fillers consisting of inert materials or medicinal agents such as vitamins or antibacterial agents (paragraph 0037). The reference differs from the instant claims insofar as it does not teach using in combination with *Citrus karna, Zanthoxylum armatum, Azadirachta indica* and *Oryza sativa* in the oral care compositions.

It would have been obvious to one of ordinary skill in the art to have added acetic acid and cinnamon-clove beads in the composition of the combined teachings of the initial four reference motivated by the desire to produce a toothpaste or toothpowder with effective inhibition of plaque and other bacteria properties as well as the ability to add medicants to the compositions by incorporating them into the cinnamon-clove beads, as taught by the secondary reference.

Claims 1-16 are rejected.

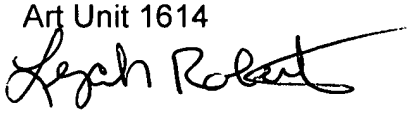
No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lezah Roberts
Patent Examiner
Art Unit 1614



Frederick Krass
Primary Examiner
Art Unit 1614